

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
_____)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, J. July 19, 2011

Sandra J. Pendergrass ("Ms. Pendergrass" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Ricky L. Pendergrass, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R. Boxberger, M.D, F.A.C.C. Based on an echocardiogram dated June 14, 2001, Dr. Boxberger attested in Part II of claimant's Green Form that Ms. Pendergrass suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$628,632.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Willie J. Sessions, M.D., stated that Ms. Pendergrass had "[m]ild to moderate [mitral regurgitation]." Dr. Sessions, however did not specify a percentage as to the level of claimant's mitral regurgitation.⁵ Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2006, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists.⁶ In audit, Dr. Gradus-Pizlo concluded

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Claimant also submitted an echocardiogram report prepared in September, 2002 by Dr. Boxberger based on her June 14, 2001 echocardiogram. In this report, Dr. Boxberger stated that claimant had "moderate mitral regurgitation based on RJA to LAA ratio of 22%."

6. The Trust originally forwarded the claim for review in or around February, 2004. Although the auditing cardiologist
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that there was no reasonable medical basis for the attesting physician's finding that Ms. Pendergrass had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Gradus-Pizlo explained, "[The] [j]et area is less than 20% of RAA. There are no area measurements on this tape."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted affidavits from Dr. Boxberger, Dan A. Francisco, M.D.,

6. (...continued)
determined there was a reasonable medical basis for Dr. Boxberger's Green Form representations, the Trust had not issued a post-audit determination prior to the court's order of May 10, 2004, which stayed the processing of certain claims for benefits. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). In September, 2005, the Trust notified claimant that, pursuant to PTO No. 5632 (August 26, 2005), her claim would be re-audited unless she notified the Trust of her election not to have her claim re-audited. Thus, in February, 2006, the Trust forwarded the claim to a second auditing cardiologist, Dr. Gradus-Pizlo, for review. Dr. Gradus-Pizlo's review is the subject of this show cause proceeding

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the claim of Ms. Pendergrass.

F.A.C.C., G. Whitney Reader, M.D., F.A.C.P., F.A.C.C., and Roger W. Evans, M.D., F.A.C.P., F.A.C.C. In his affidavit, Dr. Boxberger confirmed his previous finding that Ms. Pendergrass had moderate mitral regurgitation. Dr. Boxberger stated, "The echocardiogram tape in question shows 'moderate' mitral valve regurgitation with a RJA/LAA ratio of 22%." Dr. Francisco also found "'moderate' mitral valve regurgitation with a RJA/LAA ratio of 21%." Dr. Reader concluded that claimant had "'moderate' mitral valve regurgitation with a RJA/LAA ratio of approximately 24%." Dr. Evans also calculated "a RJA/LAA ratio of 24%." In addition, claimant submitted a "Supplemental Special Notice" sent to her by the Trust. In this notice, the Trust informed Ms. Pendergrass that, prior to the stay, her claim was reviewed by an auditing cardiologist and was found to have a "reasonable medical basis." Claimant argued, therefore, that she had established a reasonable medical basis for her claim because five (5) cardiologists independently concluded that she had moderate mitral regurgitation. Finally, claimant asserted that the auditing cardiologist "apparently did not understand the difference between her personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On September 1, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6538 (Sept. 1, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 7, 2006, and claimant submitted a sur-reply on December 6, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Pendergrass reasserts the arguments she made in contest; namely, that the opinions of Dr. Francisco, Dr. Reader, Dr. Evans, as well as the conclusion of Michael Rihner, M.D., the auditing cardiologist who reviewed the claim prior to the court-imposed stay, provide a reasonable medical basis for Dr. Boxberger's finding of moderate mitral regurgitation. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and that of the auditing cardiologist, Dr. Gradus-Pizlo.

In response, the Trust argues that the opinions provided by Dr. Francisco, Dr. Reader, and Dr. Evans fail to establish a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. The Trust also contends that inter-reader variability does not account for the discrepancies between claimant's physicians and the auditing cardiologist. Finally, the Trust states that claimant cannot rely on the results of the first audit of her claim because Ms. Pendergrass "failed to elect to stand on the results of her pre-stay audit."

In her sur-reply, claimant again argues that there is a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation and that the Trust has misinterpreted the medical literature relative to inter-reader variability.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding that Ms. Pendergrass had moderate mitral regurgitation. Specifically, Dr. Burke stated in his report:

Using representative beats in the apical four chamber view, I calculated the RJA/LAA ratios to range from 29% to 53%. Most of these representative beats were in the moderate range. Two of my calculations were in the severe range.

Using representative beats in the apical three chamber view, I calculated RJA/LAA ratios to range from 39% to 58%. These values are in the moderate to severe range of mitral regurgitation.

In conclusion, although the RJA/LAA ratio likely overestimates the severity of mitral regurgitation since the claimant has a normal left atrial size and the duration of the regurgitation in each cardiac cycle is brief, there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a., which states that Claimant suffers from moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. The attesting physician, Dr. Boxberger, reviewed the echocardiogram and found that Ms. Pendergrass had moderate mitral regurgitation. Although the Trust challenged Dr. Boxberger's findings, claimant submitted the affidavits of Dr. Boxberger and three additional physicians who determined that the echocardiogram was consistent with moderate mitral regurgitation. The Trust did not adequately respond to the findings set forth in Dr. Boxberger's affidavit. Moreover, Dr. Burke determined "the RJA/LAA ratios to range [in the apical four chamber view] from 29% to 53%" and, in the apical three chamber view, "from 39% to 58%." Although he stated that the RJA/LAA ratio overestimated the severity of claimant's mitral regurgitation, he nevertheless concluded that there was a reasonable medical basis for Dr. Boxberger's finding of mitral regurgitation. Despite an

opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Boxberger, claimant's additional physicians, and Dr. Burke each found that the RJA/LAA ratio was greater than 20%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for Dr. Boxberger's representation that Ms. Pendergrass suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim and that she consequently is entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim of Ms. Pendergrass for Matrix Benefits and the related derivative claim submitted by her spouse.